



# **Dengue Vaccine**

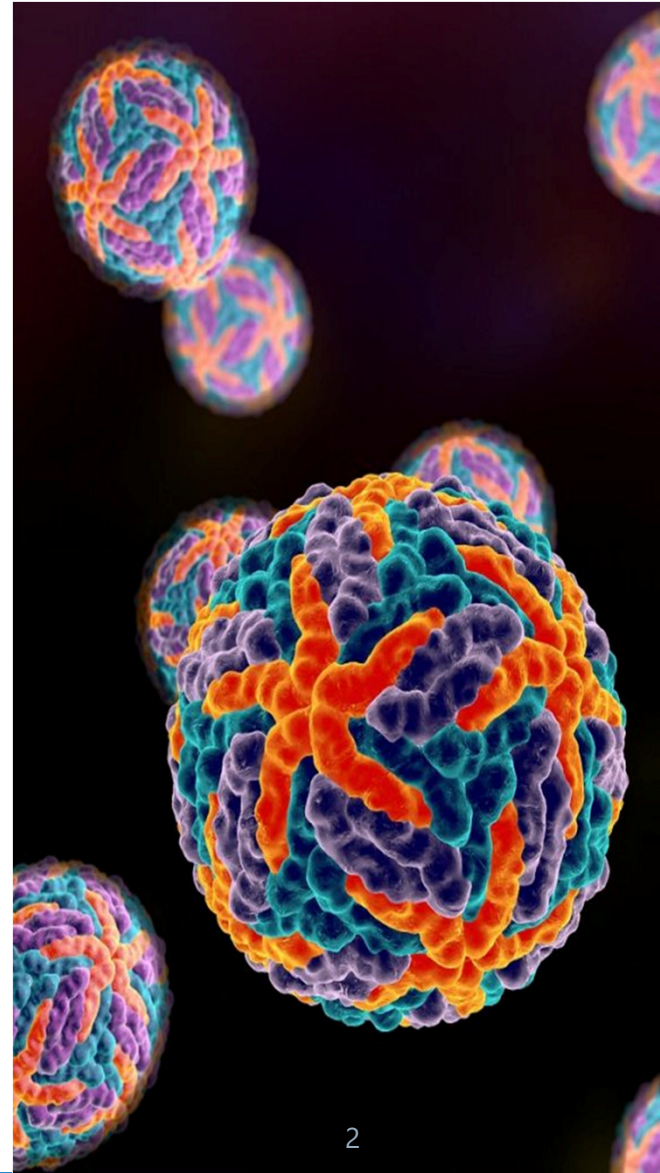
## **Evidence to recommendations framework**

**Gabriela Paz Bailey, MD, PhD, MSc**

**Dengue Branch, Division of Vector-Borne Diseases, CDC**

# Dengue

- DENV-1, 2, 3, 4
  - Lifelong DENV type-specific immunity
  - Short-term cross-immunity
- Transmitted by the *Aedes* mosquitoes
- Most frequent arboviral disease globally

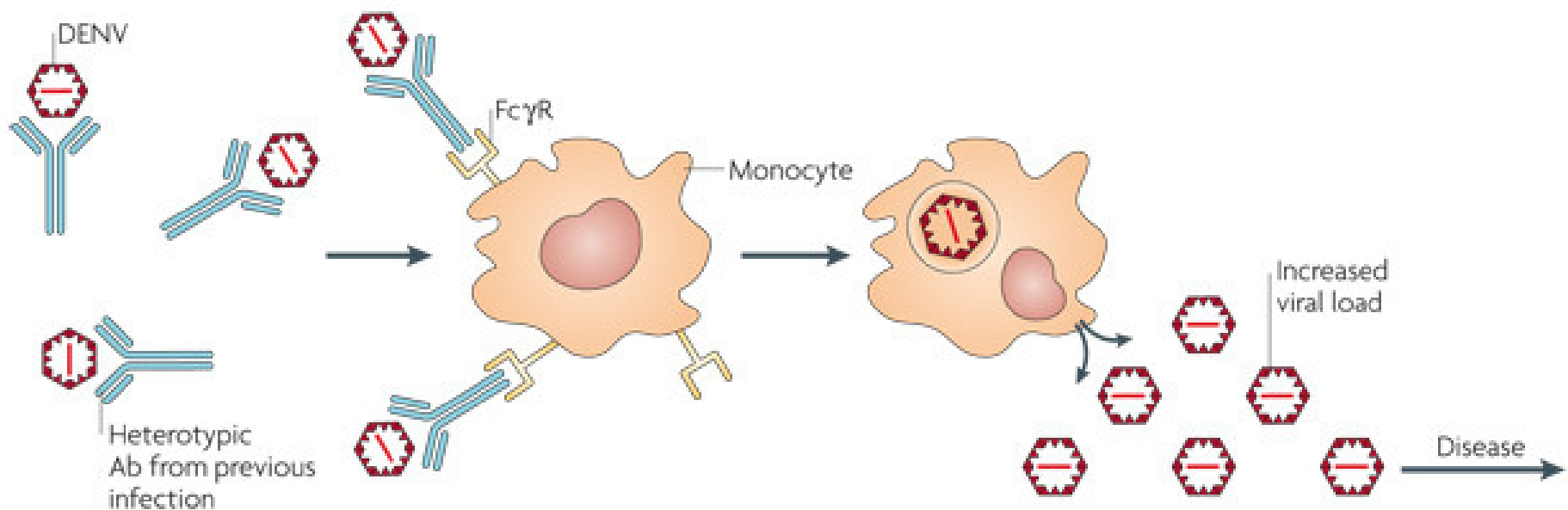


# Dengue illness

- Dengue fever can range from asymptomatic or mild to severe
- Mortality can range from 0.2% (treated) to as high as 20% (untreated)
- Causes of death: unrecognized or prolonged shock, hemorrhage, fluid overload, nosocomial sepsis

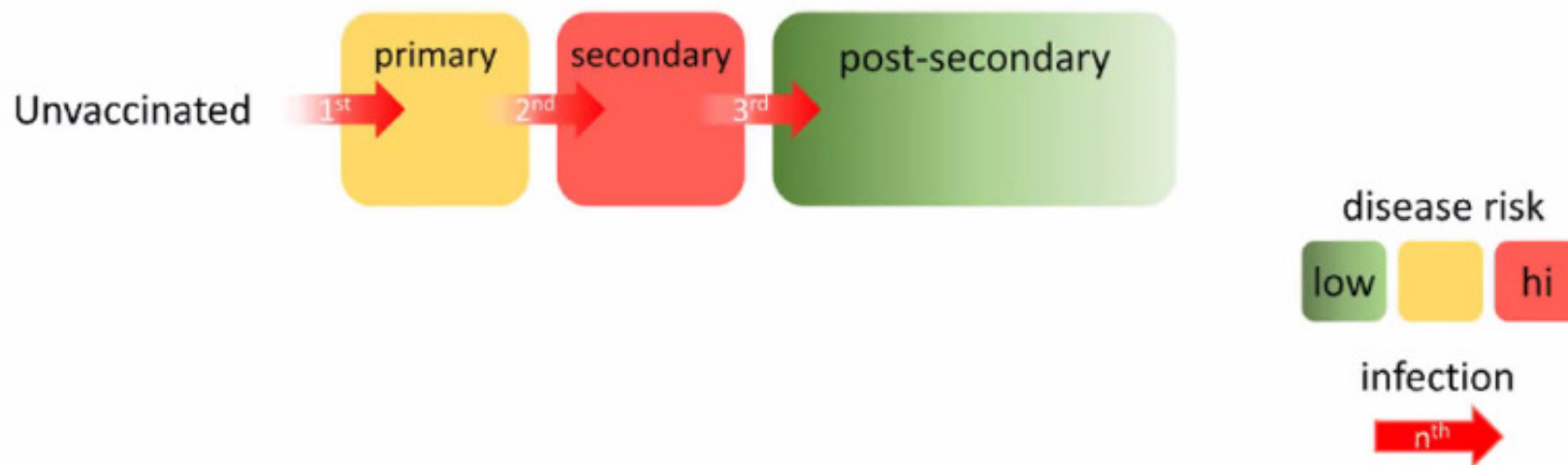


# Antibody-dependent enhancement (ADE) of dengue infection



Whitehead SS, Blaney JE, Durbin AP, Murphy BR. Prospects for a dengue virus vaccine. *Nat Rev Microbiol.* 2007;5(7):518-528. doi:[10.1038/nrmicro1690](https://doi.org/10.1038/nrmicro1690)

# Secondary dengue infection is the riskiest for poor outcomes



Flasche S, Jit M, Rodríguez-Barraquer I, et al. The Long-Term Safety, Public Health Impact, and Cost-Effectiveness of Routine Vaccination with a Recombinant, Live-Attenuated Dengue Vaccine (Dengvaxia): A Model Comparison Study. von Seidlein L, ed. *PLoS Med*. 2016;13(11):e1002181. doi:[10.1371/journal.pmed.1002181](https://doi.org/10.1371/journal.pmed.1002181)

# Dengvaxia timeline

2015

- Trial results showed increased risk of severe disease among 2-5 year-olds
- Dengvaxia licensed in the Philippines for children >9 years old.

2016

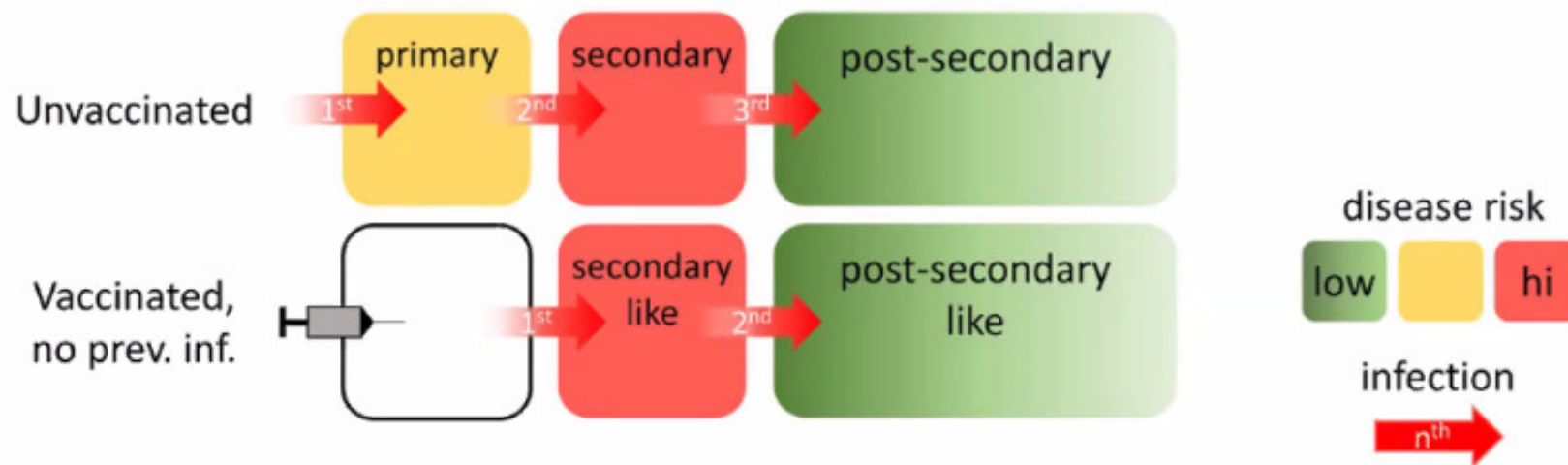
- WHO position paper: 9y and older in highly endemic areas
- Philippines starts vaccinating 1 million children ages 9-10 years

2017

- Case-cohort study showed increased risk of severe dengue and hospitalization among vaccinated seronegative children compared to controls



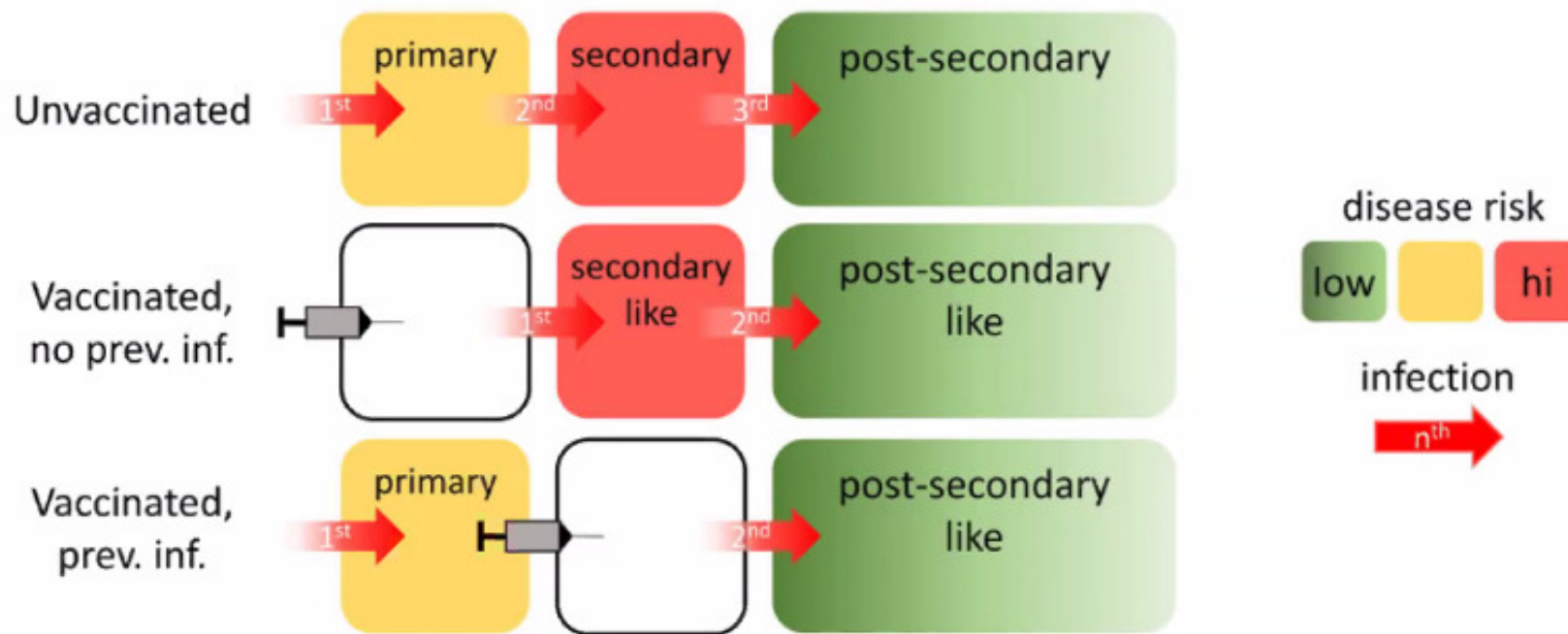
# Secondary dengue infection is the riskiest for poor outcomes



Flasche S, Jit M, Rodríguez-Barraquer I, et al. The Long-Term Safety, Public Health Impact, and Cost-Effectiveness of Routine Vaccination with a Recombinant, Live-Attenuated Dengue Vaccine (Dengvaxia): A Model Comparison Study. von Seidlein L, ed. *PLoS Med*. 2016;13(11):e1002181. doi:[10.1371/journal.pmed.1002181](https://doi.org/10.1371/journal.pmed.1002181)




# Secondary dengue infection is the riskiest for poor outcomes



Flasche S, Jit M, Rodríguez-Barraquer I, et al. The Long-Term Safety, Public Health Impact, and Cost-Effectiveness of Routine Vaccination with a Recombinant, Live-Attenuated Dengue Vaccine (Dengvaxia): A Model Comparison Study. von Seidlein L, ed. *PLoS Med.* 2016;13(11):e1002181. doi:[10.1371/journal.pmed.1002181](https://doi.org/10.1371/journal.pmed.1002181)



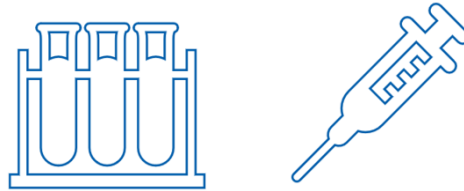
# **The Philippines experience: no screening before vaccination**

- WHO revised their recommendations vaccine only be given to children with laboratory-confirmed past dengue
  - Philippines had already vaccinated almost 1 million children without doing any testing
  - The suspension of the program broke public trust in the dengue vaccine and vaccines in general
  - Hospitalized and severe dengue cases that occur following vaccination will be a mixture of breakthrough cases from seropositive and cases from those seronegative at vaccination
  - Most dengue hospitalizations in the Philippines were due to breakthrough disease, baseline disease and a smaller percentage were vaccine-induced
- 

# FDA Licensing of first dengue vaccine 2019



# Test performance guidance for pre-vaccination screening



- **98%** specific

- **75%** sensitive



# Evidence to Recommendations Framework



# Evidence to Recommendations (EtR) Framework

EtR Domain	Question
Public Health Problem	<ul style="list-style-type: none"><li>• Is the problem (<i>Dengue</i>) of public health importance?</li></ul>
Benefits and Harms	<ul style="list-style-type: none"><li>• How substantial are the desirable anticipated effects of the intervention (<i>dengue vaccine</i>)?</li><li>• How substantial are the undesirable anticipated effects?</li><li>• Do the desirable effects outweigh the undesirable effects?</li></ul>
Values	<ul style="list-style-type: none"><li>• Does the target population feel the desirable effects are large relative to the undesirable effects?</li><li>• Is there important variability in how patients value the outcomes?</li></ul>
Acceptability	<ul style="list-style-type: none"><li>• Is the intervention acceptable to key stakeholders?</li></ul>
Feasibility	<ul style="list-style-type: none"><li>• Is the intervention feasible to implement?</li></ul>
Resource Use	<ul style="list-style-type: none"><li>• Is the intervention a reasonable and efficient allocation of resources?</li></ul>
Equity	<ul style="list-style-type: none"><li>• What would be the impact of the intervention on health equity?</li></ul>

# Policy Question

**Question:** Should 3-doses of Dengvaxia be administered routinely to persons 9-16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas?

# Public Health Problem

## Is dengue disease of public health importance?

- *Are the consequences of dengue serious?*
- *Is dengue urgent?*
- *Are a large number of people affected by dengue?*
- *Are there populations disproportionately affected by dengueCOVID-19?*

☐ No   ☐ Probably no   ☐ Probably yes   ☐ Yes   ☐ Varies   ☐ Don't know



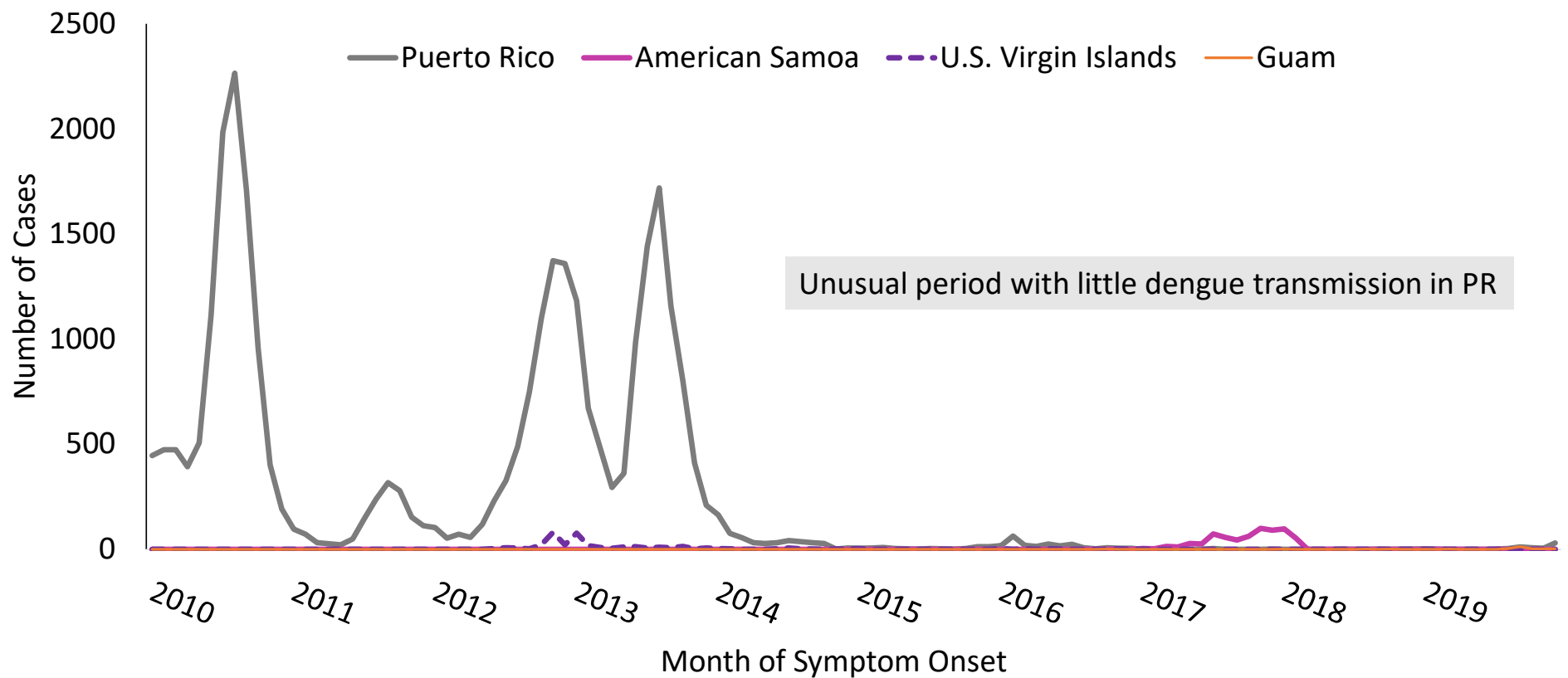


# Dengue endemic areas in the United States

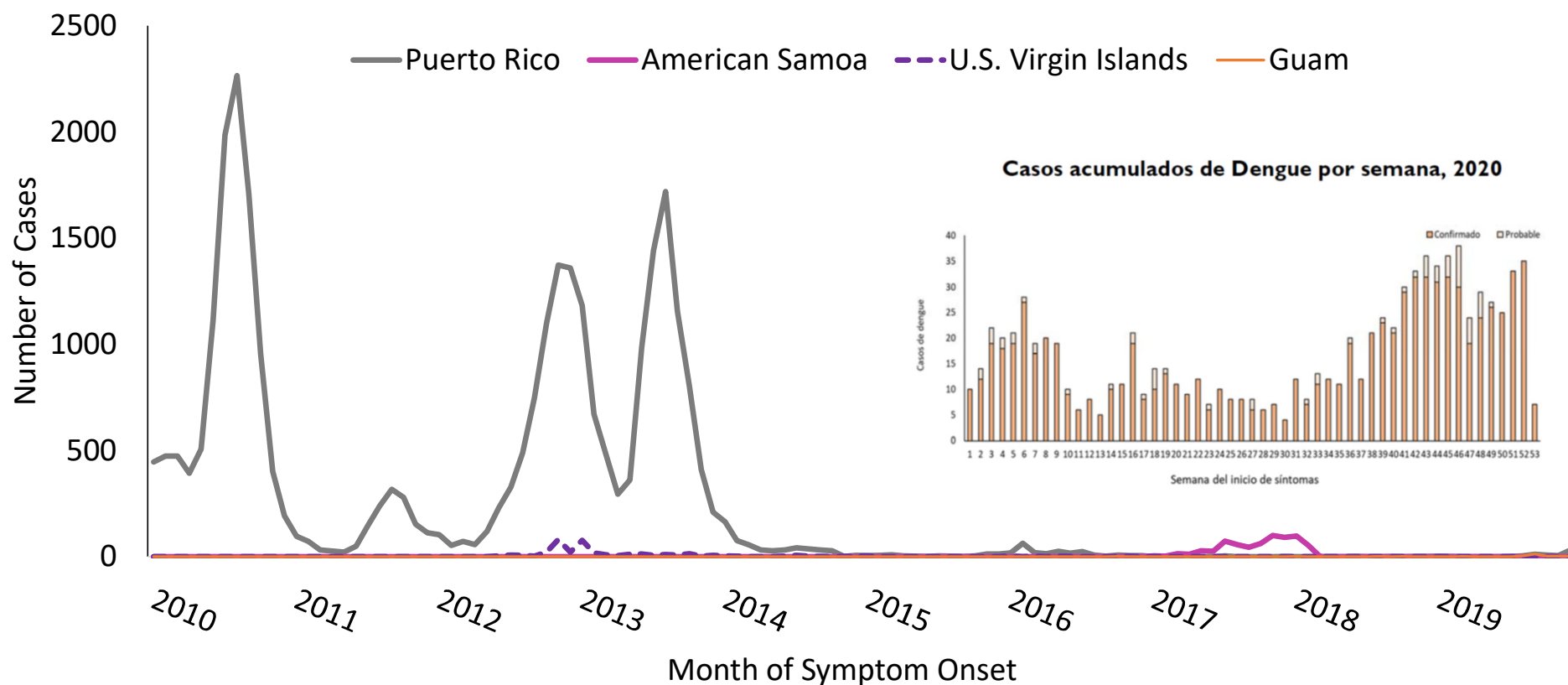
>91% of the population at risk for locally-acquired dengue is in Puerto Rico

Country/Area	Level of dengue risk	Population
U.S. States	Sporadic/uncertain	
Territories and freely associated states		
American Samoa	Frequent/Continuous	55,465 (1.6%)
Puerto Rico	Frequent/Continuous	3,194,000 (91.6%)
US Virgin Islands	Frequent/Continuous	106,977 (3%)
Guam	Sporadic/uncertain	
Northern Mariana Islands	Sporadic/uncertain	
Micronesia		
Federated States of Micronesia	Frequent/Continuous	112,640 (3.2%)
Palau	Frequent/Continuous	17,907 (0.5%)
Marshall Islands	Sporadic/uncertain	
Total population at risk		3,486,989

# 95% of dengue cases in U.S. territories occur in Puerto Rico

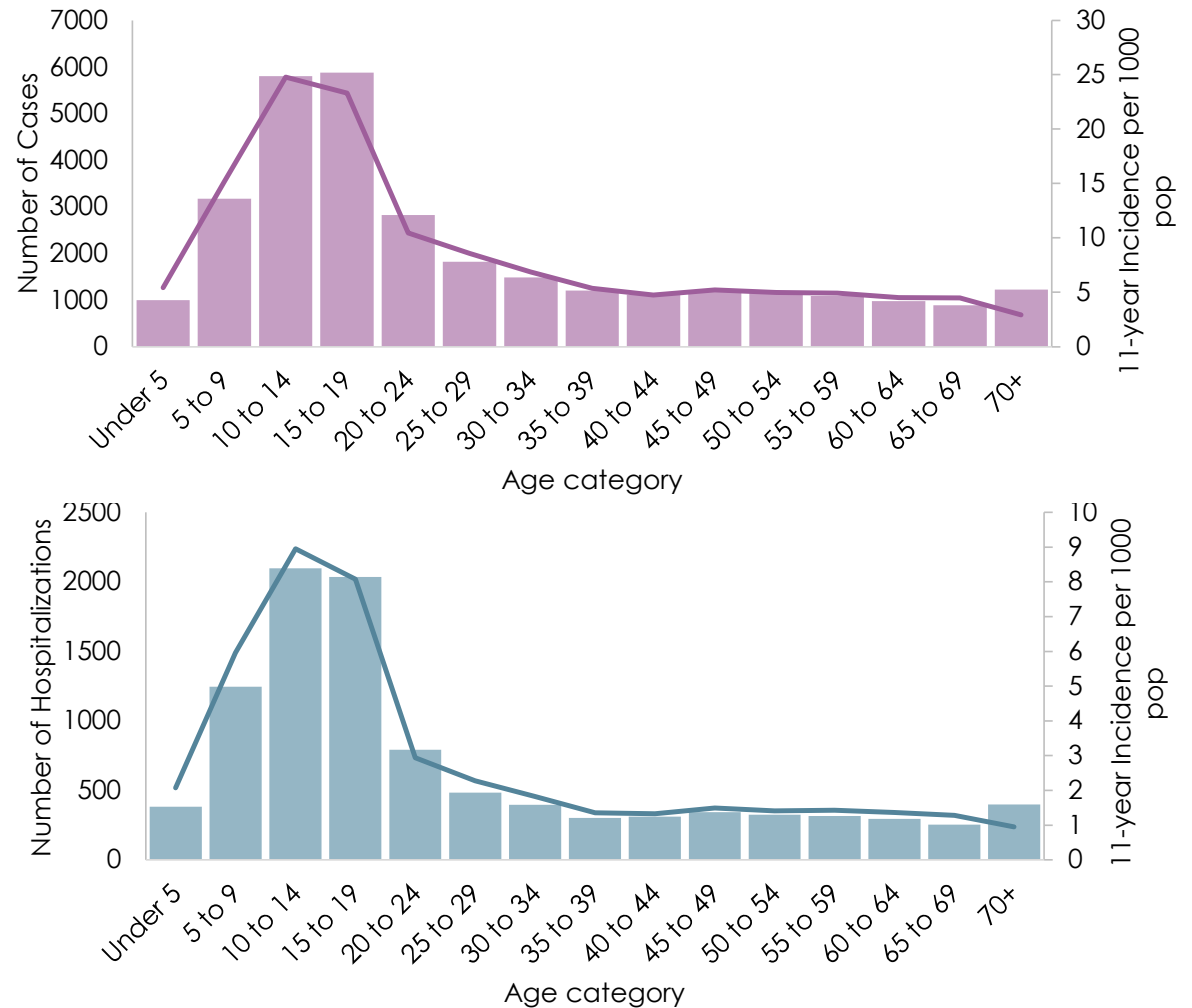


# 95% of dengue cases in U.S. territories occur in Puerto Rico



# Dengue virus cases and hospitalizations by age, Puerto Rico, 2010–2020\*

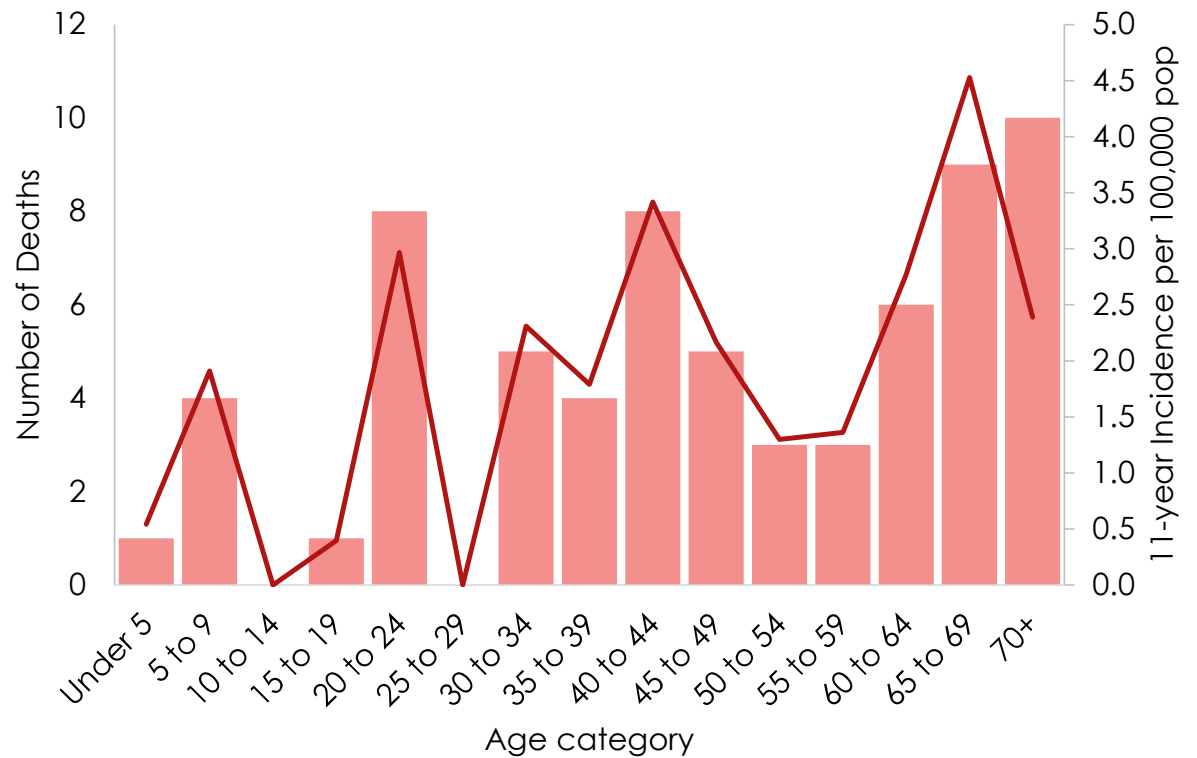
**Highest incidence of cases and hospitalizations among children 10–19 years old**



\*Includes confirmed and probable cases reported to Arbonet, National Arbovirus Surveillance System.  
2020 data is preliminary; accessed Feb 4, 2021

# Dengue virus **deaths** by age, Puerto Rico, 2010–2020\*

**Most dengue deaths (88%; 61/69)  
occurred among adults ≥20 years old**



\*Includes confirmed and probable cases reported to Arbonet, National Arbovirus Surveillance System.  
2020 data is preliminary; accessed Feb 4, 2021

# Dengue Seroprevalence in Puerto Rico

- Argüello et al: 10-18 years<sup>1</sup>
  - 2007 (n=345): 50% (95% CI: 44–56)
- Sanofi Pasteur trial data: 9-16 years<sup>2</sup>
  - 2009 (n=106): **78%** (95% CI: 69–86)
  - 2011 (n=152): **56%** (95% CI: 47–64)
- COPA project<sup>3</sup>: 9-16 years, DENV PRNT>10
  - 2018 (n=414): **59%** (95% CI: 54–63)
    - 13% primary DENV; 46% secondary DENV
    - 50% seropositive at age 9 years

1. Argüello DF, et al. AJTMH. 2015 Mar 4;92(3):486-91.

2. L'Azou M, et al. TRSTMH. 2018 Apr 1;112(4):158-68.

3. Unpublished.

# Public Health Problem:

## Work Group Interpretation

Is dengue disease of public health importance?

☐ No    ☐ Probably no    ☐ Probably Yes    ☒ Yes    ☐ Varies    ☐ Don't know





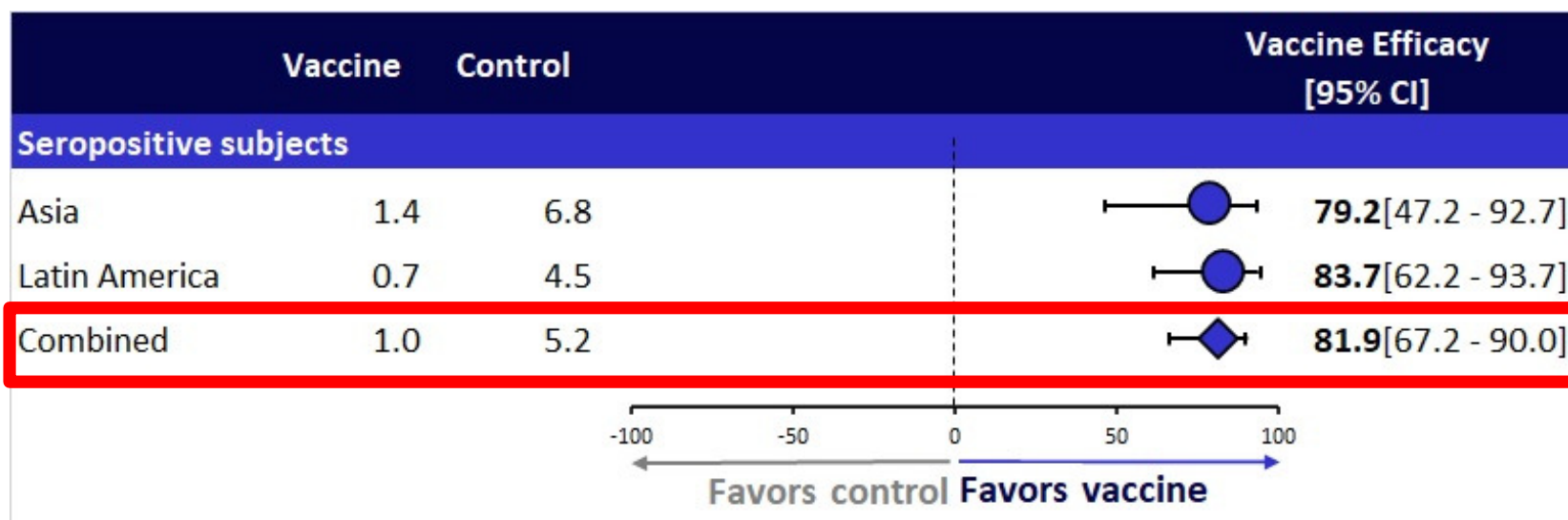
# Benefits and Harms

How substantial are the desirable anticipated effects?

☐ Minimal   ☐ Small   ☐ Moderate   ☐ Large   ☐ Varies   ☐ Don't know

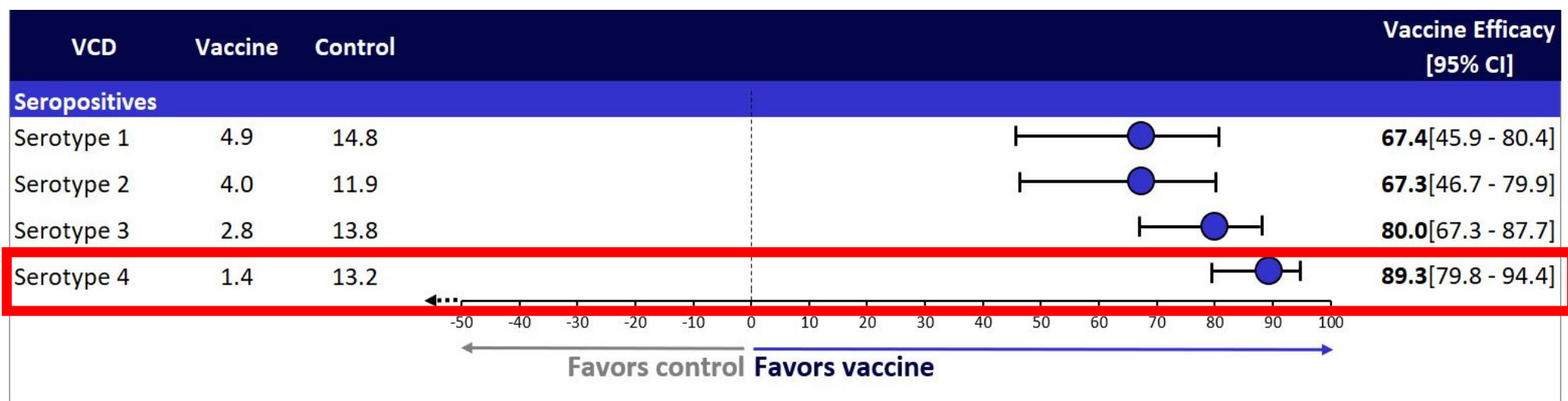


# Efficacy against virologically confirmed dengue (VCD) seropositive participants 9-16 years

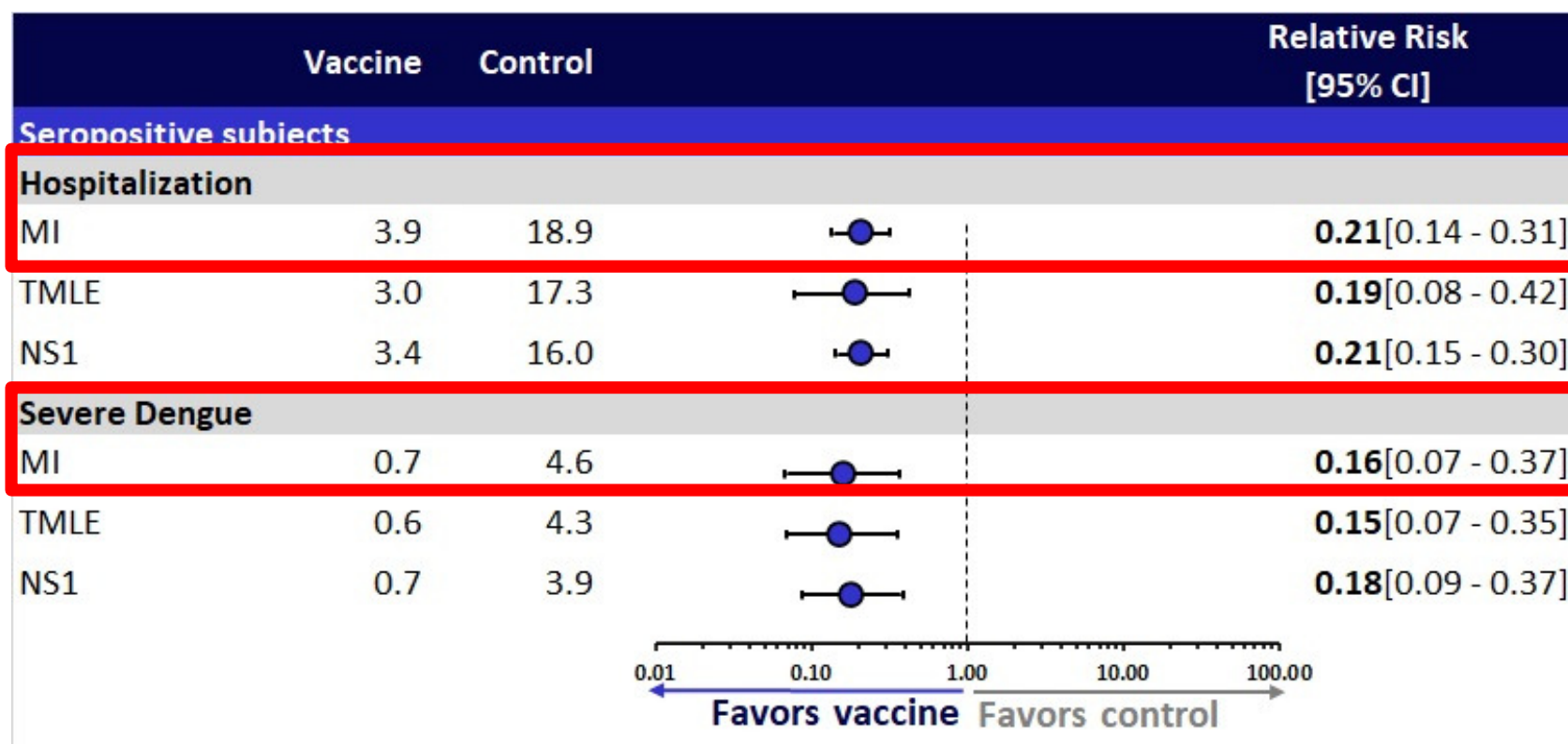


Hadinegoro SR et al. N Engl J Med 2015;373:1195-1206.

# Efficacy against VCD among dengue seropositive participants 9-16 years



# Efficacy against hospitalization and severe dengue seropositive participants 9-16 years



# How substantial are the desirable anticipated effects?

☐ Minimal   ☐ Small   ☒ Moderate   ☐ Large   ☐ Varies   ☐ Don't know

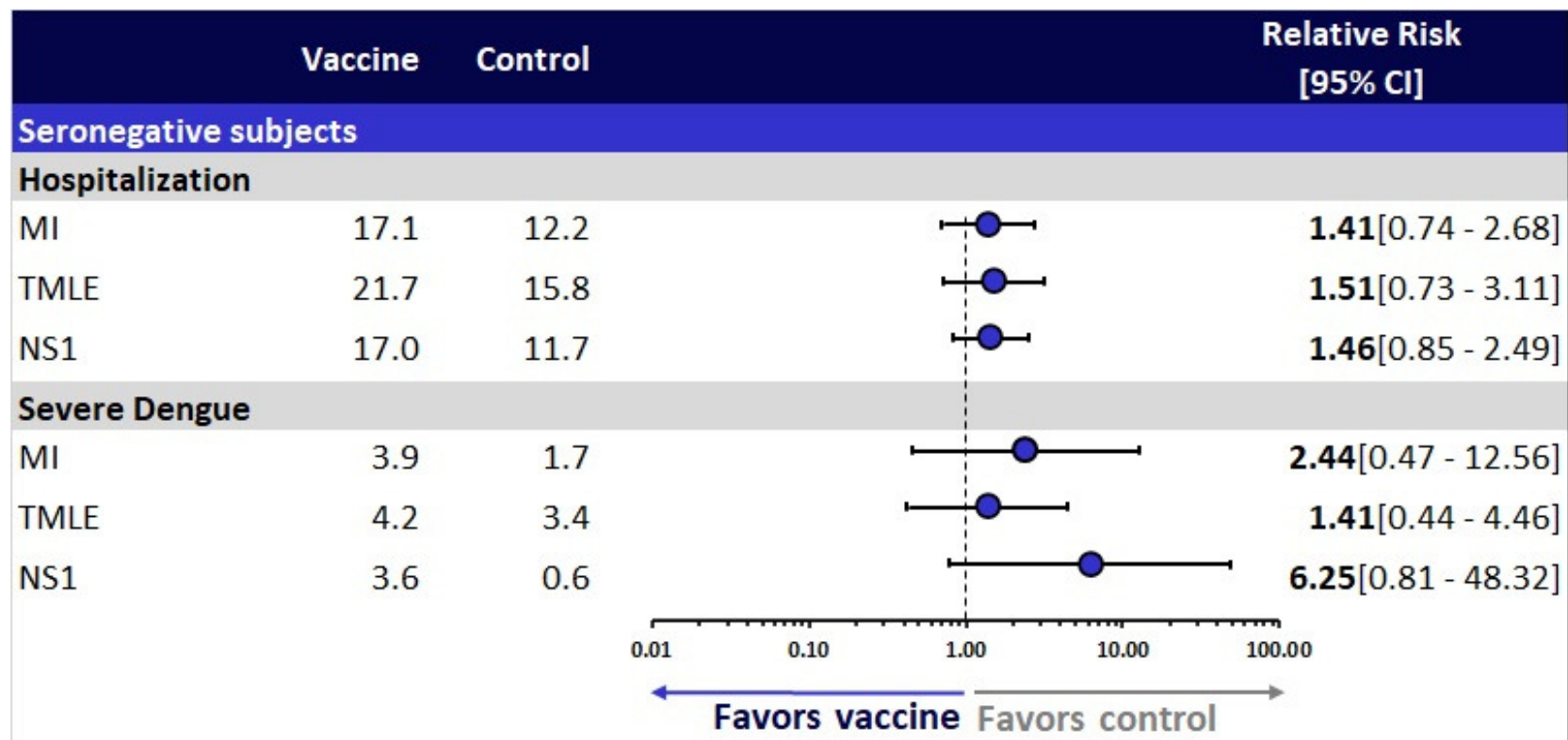


How substantial are the undesirable anticipated effects?

☐ Minimal    ☐ Small    ☐ Moderate    ☐ Large    ☐ Varies    ☐ Don't know



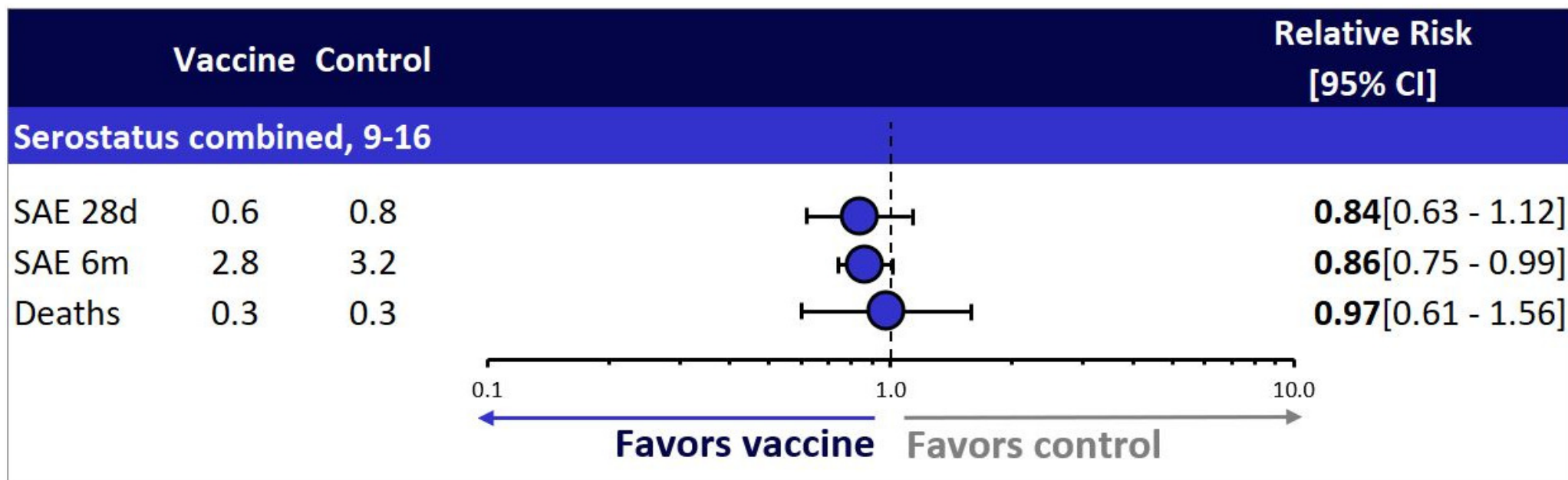
# Risk of hospitalization and severe dengue when vaccinating a seronegative child 9-16 years



Sridhar, S, et al. N Engl J Med. 2018 Jul 26; 379(4):327-340



# Severe adverse events and deaths among participants 9-16 years, serostatus combined



Gustavo Dayan, Sanofi, personal communication.

# How substantial are the undesirable anticipated effects?

☐ Minimal ☒ Small ☐ Moderate ☐ Large ☐ Varies ☐ Don't know



# Do the desirable effects outweigh the undesirable effects?

- ☐ Favors intervention
- ☐ Favors comparison
- ☐ Favors both
- ☐ Favors neither
- ☐ Varies
- ☐ Don't know



# Benefits and harms

- Benefits of Dengvaxia
  - Efficacy against symptomatic virologically confirmed dengue (82% CI: 67-90)
  - Efficacy against dengue hospitalizations 79% (CI:69-86)
  - Efficacy against severe dengue 84% (CI:63-93)
- Harms of Dengvaxia
  - Increased risk of vaccine-induced hospitalization if a seronegative child is vaccinated after a false-positive laboratory test

# Population impact of screen and vaccinate strategy

- Agent-based model of dengue transmission with humans and mosquitoes represented as agents
- Calibrated to simulate dengue transmission in Puerto Rico
- Compares pre-vaccination screening and subsequent vaccination of seropositive 9-year-olds to the status quo
- Model population followed for 10 years keeping track of dengue infections, hospitalizations and deaths
- Prevalence at age 9 years of age of 50% and 30%
- Population level benefits: symptomatic and hospitalized cases averted
- Risks: vaccine –induced hospitalizations among dengue-naïve individuals

# Population-level impacts of the intervention in Puerto Rico

Total numbers of symptomatic and hospitalized cases as well as cases averted and additional hospitalizations among vaccinees.

Time frame modeled: 10 years

Strategy: testing and vaccinating cohorts of test-positive 9-year-old children in Puerto Rico annually

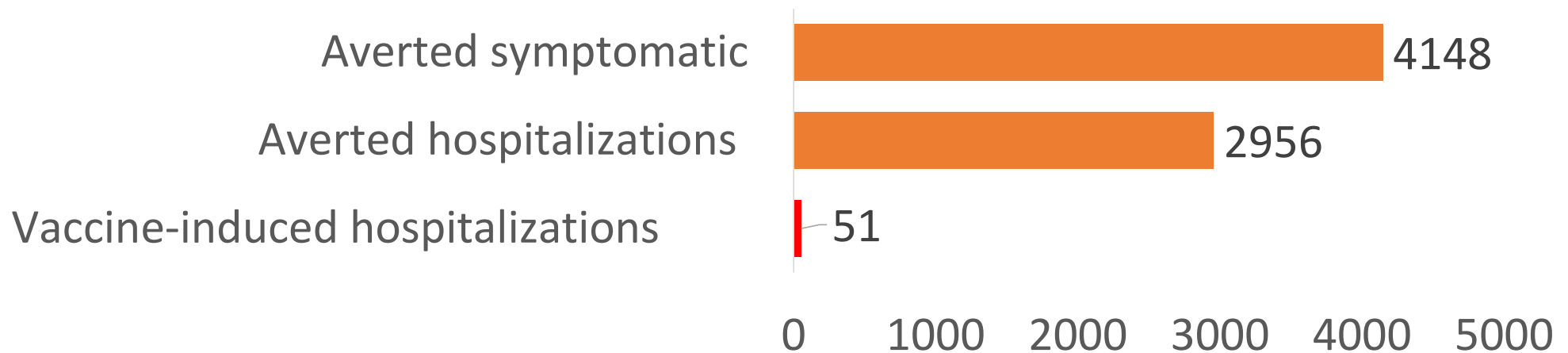
Test performance: sensitivity = 0.75 and specificity = 0.98.

	Baseline		Tested	Vaccinated	Averted		Additional	Ratio
Prior exposure in 9-yr-olds	Symptomatic	Hospitalizations			Symptomatic	Hospitalizations	Hospitalizations	averted/additional
30%	221751	51278	317823	61825	1551	1262	112	11/1
50%	260218	60663	317814	102884	4148	2956	51	57/1
60%	271711	63807	317809	125127	5538	4295	28	152/1

# Benefits and harms of vaccination among a 10-year cohort of 9-year-old children 50% seroprevalence

Screening test 75% sensitive and 98% specific

50% seroprevalence



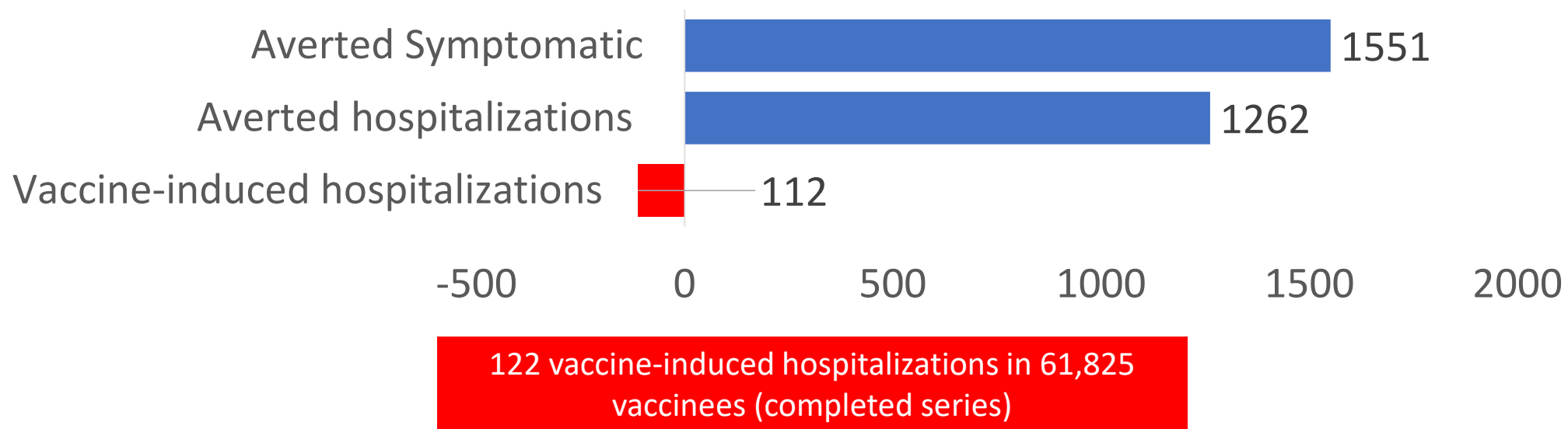
51 vaccine-induced hospitalizations in  
102,884 vaccinees (completed series)



# Benefits and harms of vaccination among a 10-year cohort of 9-year-old children 30% seroprevalence

Screening test 75% sensitive and 98% specific

30% seroprevalence



# Summary of population benefits and harms of vaccination among a 10-year cohort of 9-year-old children

## 50% seroprevalence

- Risks
  - 51 vaccine-induced hospitalizations among seronegative children
- Benefits
  - 4148 fewer symptomatic cases
  - 2956 fewer hospitalizations

## 30% seroprevalence

- Risks
  - 112 vaccine-induced hospitalizations among seronegative children
- Benefits
  - 1551 fewer symptomatic cases
  - 1262 fewer hospitalizations

## **Interpretation benefits and harms**

- Shows positive balance for benefits versus harms
- Balance of risk and benefits varies by seroprevalence

# Do the desirable effects outweigh the undesirable effects?

☒ Favors intervention

☐ Favors comparison

☐ Favors both

☐ Favors neither

☐ Varies

☐ Don't know



# What is the overall certainty of the evidence?

## Effectiveness of the intervention

☐ 4 (very low)   ☐ 3 (low)   ☐ 2 (moderate)   ☐ 1 (high)

## Safety of the intervention

☐ 4 (very low)   ☐ 3 (low)   ☐ 2 (moderate)   ☐ 1 (high)



# What is the overall certainty of the evidence?

## Effectiveness of the intervention

☐ 4 (very low)   ☐ 3 (low)   ☐ 2 (moderate)   ☒ 1 (high)

## Safety of the intervention

☐ 4 (very low)   ☐ 3 (low)   ☒ 2 (moderate)   ☐ 1 (high)



# Values

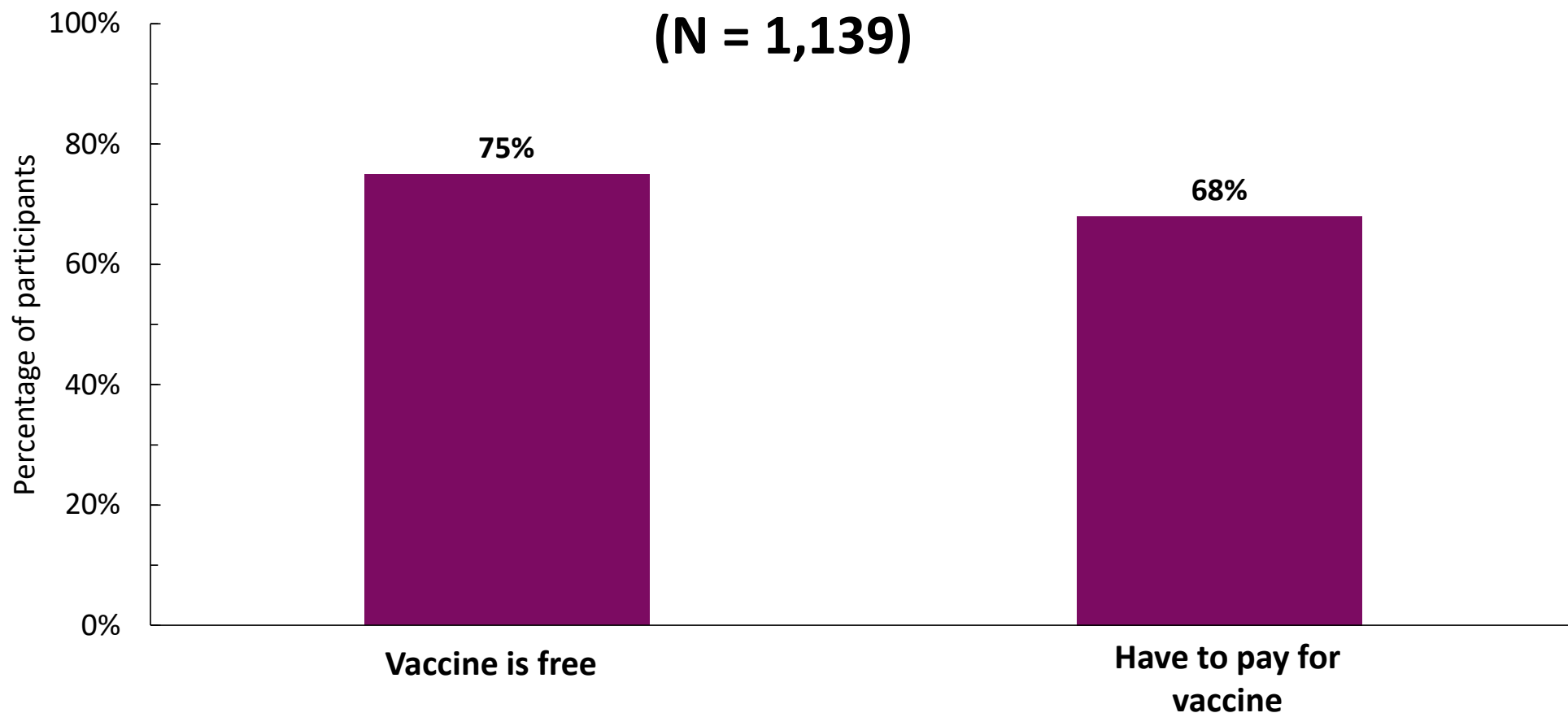
**Does the target population feel that the desirable effects are large relative to undesirable effects?**

☐ No    ☐ Probably no    ☐ Probably Yes    ☐ Yes    ☐ Varies    ☐ Don't know



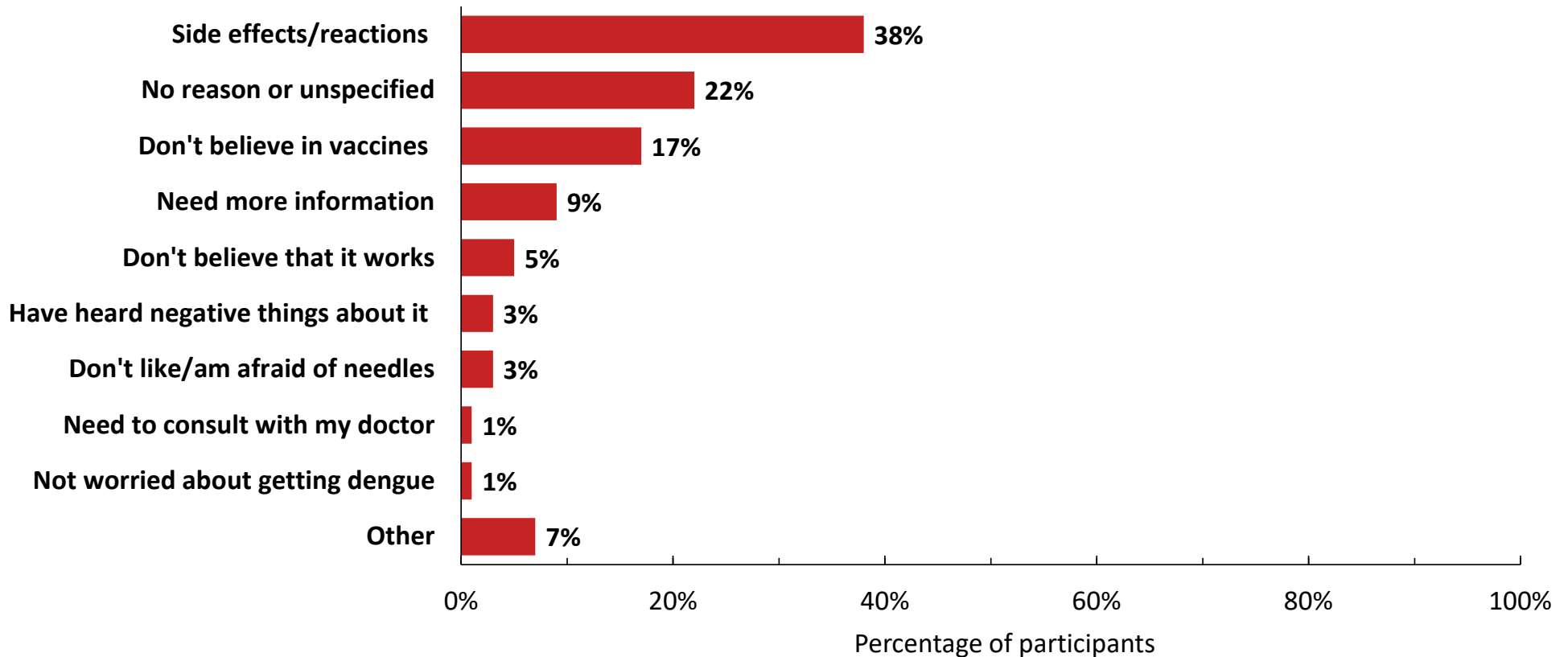
# Interest in vaccinating children against dengue among adults, Ponce, Puerto Rico

(N = 1,139)





# Reasons would not/unsure vaccinate, Ponce, PR 342/1139



\*Includes participants who would not receive dengue vaccine for themselves and/or for their children where applicable.

**Does the target population feel that the desirable effects are large relative to undesirable effects?**

☐ No   ☐ Probably no   ☒ Probably Yes   ☐ Yes   ☐ Varies   ☐ Don't know



# Is there important uncertainty about or variability in how much people value the main outcomes?

- Important uncertainty or variability
- Probably important uncertainty or variability
- Probably not important uncertainty or variability
- Not important uncertainty or variability
- No known undesirable outcomes



# Acceptability

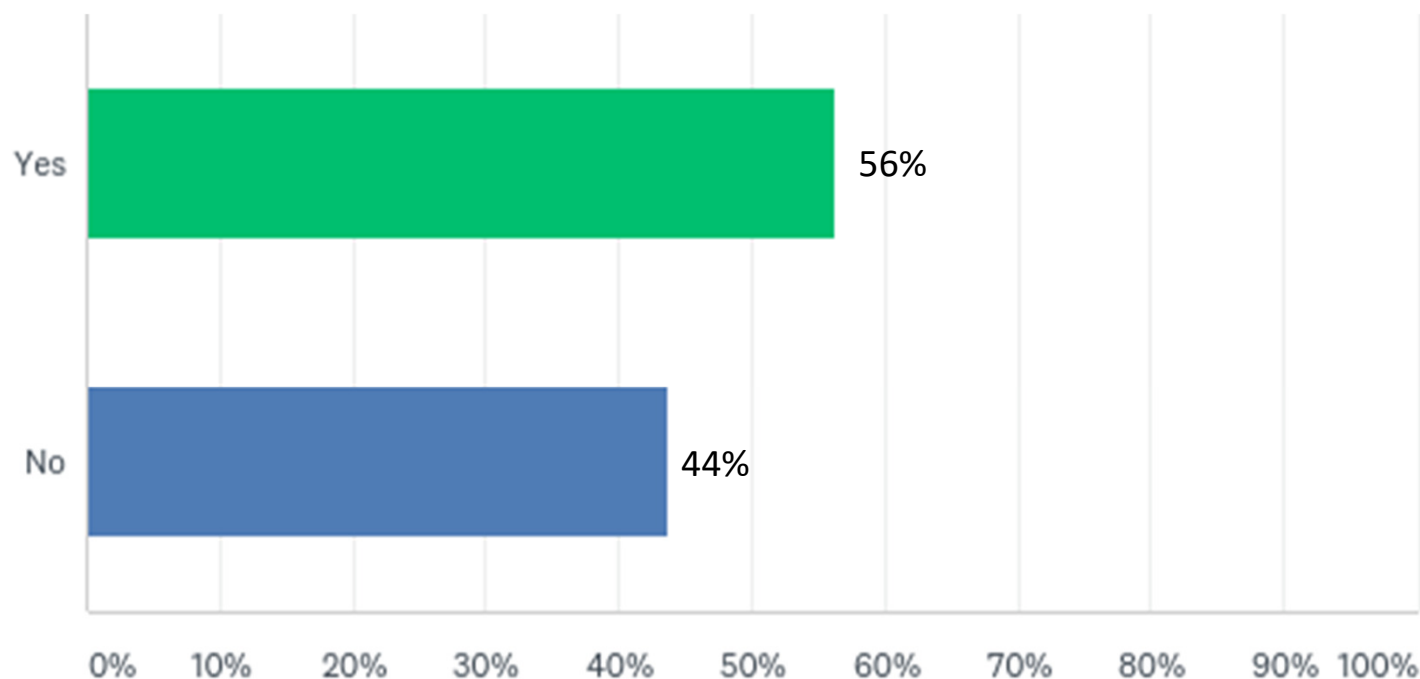
Is the intervention acceptable to key stakeholders?

☐ No    ☐ Probably no    ☐ Probably Yes    ☐ Yes    ☐ Varies    ☐ Don't know



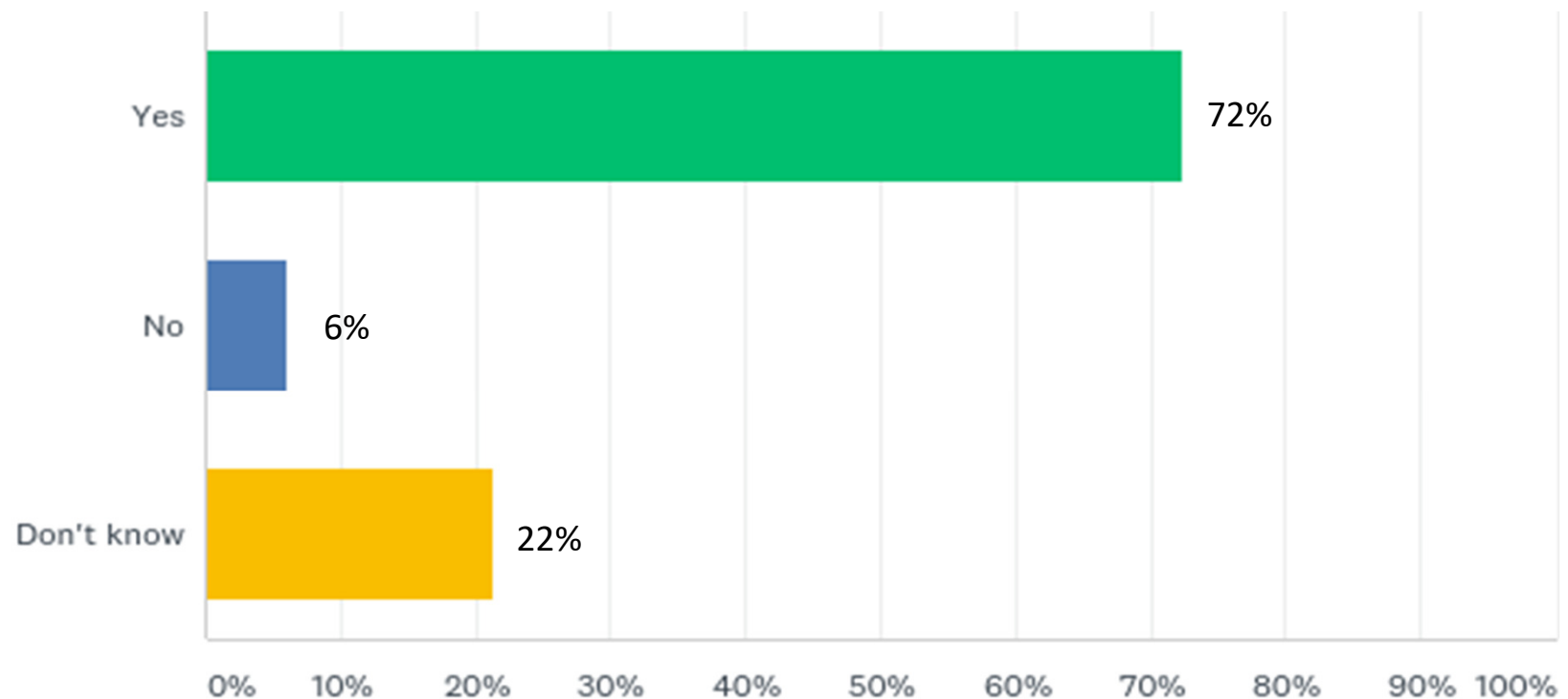
# Survey to pediatricians in Puerto Rico, 2020

Do you know there is an FDA approved vaccine for dengue known as Dengvaxia? (n=109)



# Survey to pediatricians in Puerto Rico, 2020

Assuming a laboratory test with acceptable specificity were available, would you recommend Dengvaxia to your pediatric patients? (n=109)



# Is the intervention acceptable to key stakeholders?

☐ No   ☐ Probably no   ☒ Probably Yes   ☐ Yes   ☐ Varies   ☐ Don't know



# Feasibility

Is the intervention feasible to implement?

☐ No    ☐ Probably no    ☐ Probably Yes    ☐ Yes    ☐ Varies    ☐ Don't know

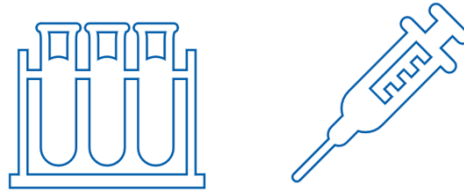




# Dengvaxia feasibility considerations

- Three doses at 0, 6 and 12 months
- Education of providers and parents about Dengvaxia efficacy and safety
  - Tested counseling materials
  - Vaccine cost
  - Out of pocket
- Screening before vaccination
  - There are tests available with acceptable performance
  - Implementation of point of care in Puerto Rico is challenging
  - None of the tests with adequate performance are FDA approved but can be implemented under CLIA
  - Cost coverage of test by insurance and Medicaid
  - Extra visits

# Test performance guidance for pre-vaccination screening



- Provide minimum performance as opposed to optimal/minimal
- Test should have sensitivity  $\geq 75\%$  and a specificity of  $\geq 98\%$
- The positive predictive value (PPV) should be  $\geq 90\%$
- A negative predictive value of  $\geq 75\%$  to minimize missing persons who would potentially benefit from the vaccine
- Sequential testing may be an option as more IgG tests are available to improve specificity  $>98\%$

# Provider counseling on risk/benefit for Dengvaxia

- Risk of disease: Dengue is endemic in Puerto Rico. The risk of getting dengue more than once while living on the island is high. Children 10-19 years are at highest risk for dengue illness and hospitalization.
- Dengue can be severe and if untreated fatal, and it remains a huge problem in Puerto Rico, especially among children 10-19 years.
- Intervention:
  - Benefit: For children with past dengue infection, Dengvaxia **reduced hospitalizations** in children 9-16 by about 80%.
  - Risk: In children without previous dengue infection, Dengvaxia **increases the risk of hospitalization** for dengue because it can enhance the immune response to that first dengue infection. The risk is similar to what a child faces when living in an endemic area and being naturally exposed to dengue multiple times.
- How do we reduce this risk:
  - Children must have serologic evidence of a previous dengue infection to be eligible for vaccination.

# Is the intervention feasible to implement?

☐ No   ☐ Probably no   ☒ Probably Yes   ☐ Yes   ☐ Varies   ☐ Don't know



# Resource Use

**Is the intervention a reasonable and efficient allocation of resources?**

☐ No    ☐ Probably no    ☐ Probably Yes    ☐ Yes    ☐ Varies    ☐ Don't know



# Cost-effectiveness analyses of Dengvaxia use in Puerto Rico

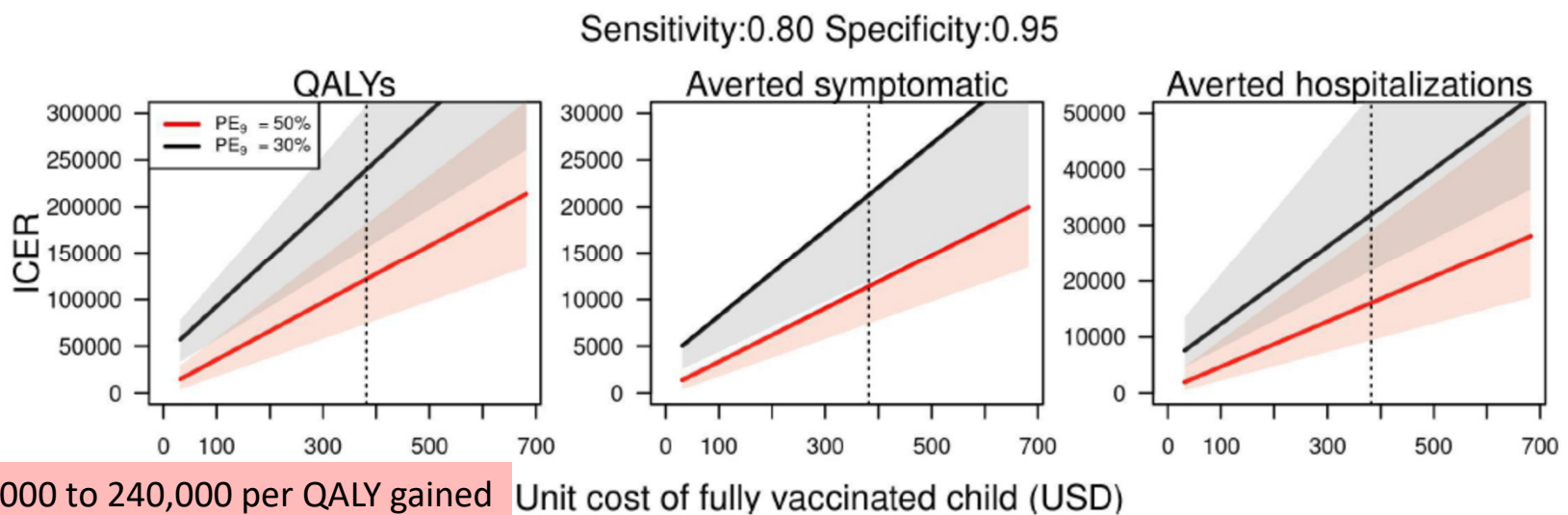
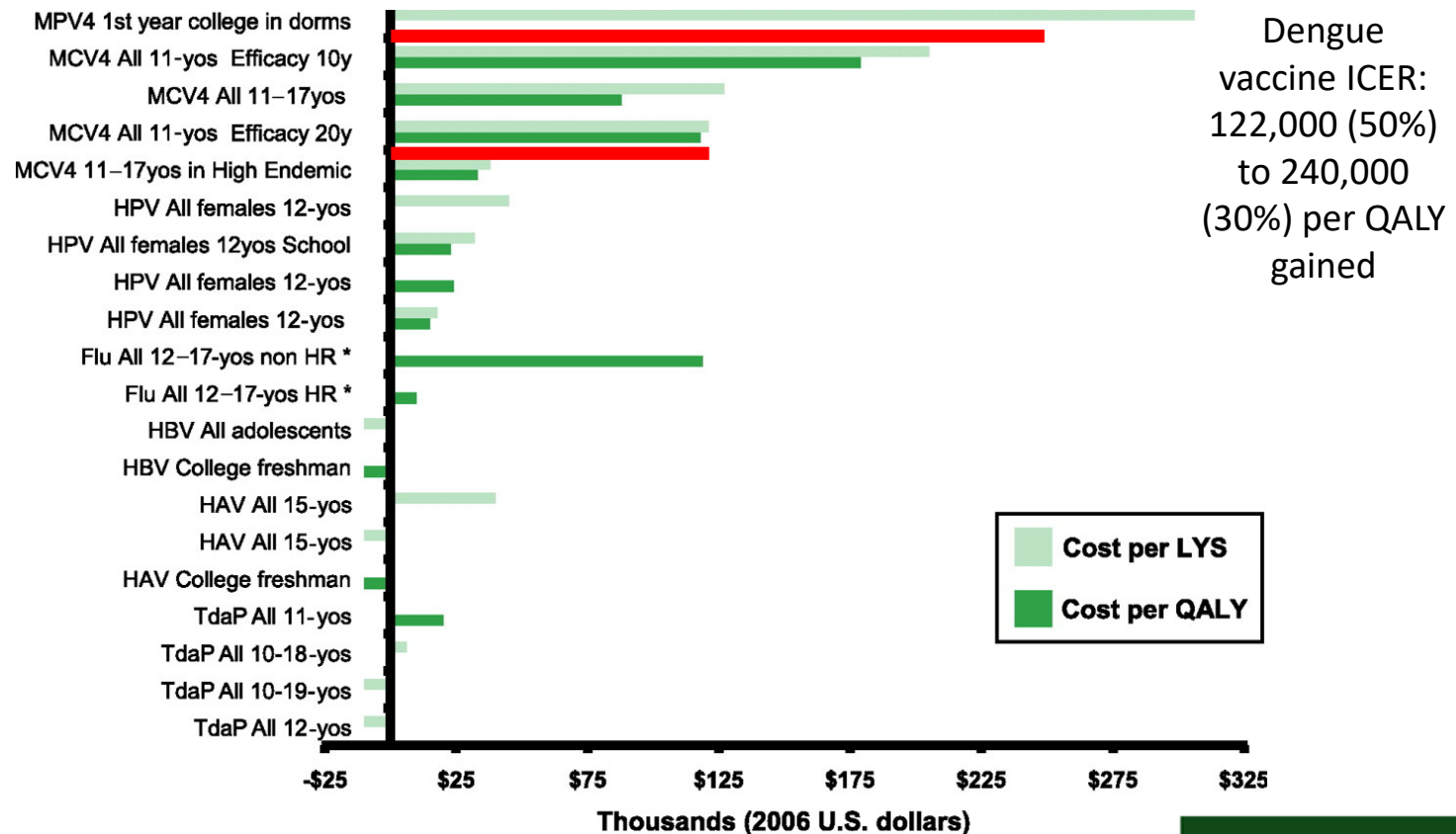


Figure 5. ICER of pre-vaccination screening strategy in Puerto Rico at different costs of vaccination (total cost for three doses per person), assuming a unit cost of serological screening of 30 USD. Dotted line represents the baseline assumption of vaccine cost (382 USD). All costs in 2019 USD.

- Espana G, Leidner A, Waterman S, Perkins A. Cost-effectiveness of Dengue Vaccination in Puerto Rico. <https://www.medrxiv.org/content/10.1101/2020.10.07.20208512v1>

# Comparison of incremental cost effectiveness ratio for Dengvaxia to other vaccines



Ismael R. Ortega-Sanchez et al. Pediatrics 2008;121:S63-S78

©2008 by American Academy of Pediatrics

**PEDIATRICS®**

# Is the intervention a reasonable and efficient allocation of resources?

☐ No    ☐ Probably no    ☒ Probably Yes    ☐ Yes    ☐ Varies    ☐ Don't know





# Equity

What would be the impact on health equity?

- ☐ Reduced
- ☐ Probably reduced
- ☐ Probably no impact
- ☐ Probably increased
- ☐ Increased
- ☐ Varies
- ☐ Don't know



# Disparities between Puerto Ricans and other US citizens in healthcare

Puerto Rico has the lowest  
Medicaid and Medicare per  
capita annual spending

Mosquito-borne diseases

Natural disasters



# Considerations to ensure that health inequities are reduced with Dengvaxia

---

Health insurance coverage for vaccine and lab test

Diagnostic testing should be economical

- For the very poor, that cannot pay fees, public funds need to be available and accessible

Multiple visits to healthcare providers for diagnostic testing and vaccine eligibility may be a greater burden for low-income families because of transportation costs and missed days of work.

Strategies to reduce the number of visits are needed.

# What would be the impact on health equity?

- ☐ Reduced
- ☐ Probably reduced
- ☐ Probably no impact
- ☒ Probably increased
- ☐ Increased
- ☐ Varies
- ☐ Don't know



# Balance of consequences

- Undesirable consequences *clearly outweigh* desirable consequences in most settings
- Undesirable consequences *probably outweigh* desirable consequences in most settings
- The balance between desirable and undesirable consequences is *closely balanced or uncertain*
- Desirable consequences *probably outweigh* undesirable consequences in most settings
- Desirable consequences *clearly outweigh* undesirable consequences in most settings
- There is insufficient evidence to determine the balance of consequences



Is there sufficient information to move forward with a recommendation?

☒ Yes

☐ No



Questions?

# Policy options for ACIP

- ACIP does not recommend the intervention (Intervention may be used within FDA licensed indications)
- ACIP recommends the intervention for individuals based on shared clinical decision-making
- ACIP recommends the intervention





# Option 1: ACIP does not recommend

## Cons

- A vaccine proven to protect persons with prior dengue infection will not be available to US citizens
- Puts off making difficult decision that will be needed for the next dengue vaccine approved by FDA
- Discourages vaccine manufacturers

## Pros

- Avoids a complicated implementation in the middle of COVID vaccinations programs

# Routine versus shared decision making

Attribute	Routine recommendation	Shared decision making
Reduction dengue transmission	Unlikely in the short term. Greater impact for DENV4.	No reduction in dengue transmission.
Disease severity	Of all dengue hospitalizations, 6% hospitalizations will be averted in a 10- year period (80% coverage and 50% seroprevalence at age 9y).	No measurable benefit in reducing hospitalizations.
Harms	For every 57 hospitalizations prevented 1 additional hospitalization would occur due to the vaccine.	Coverage will be low and among a selected group of patients so adverse events unlikely.

# Routine versus shared decision making

Attribute	Routine recommendation	Shared decision making
Cost	Coverage of screening test and vaccine by insurance companies and VFC/Medicaid. Minimizes cost to families.	Coverage of vaccine, uncertain coverage of the test without documented medical indication by a provider. Possibly higher out of pocket expenses.
Implementation and feasibility	<p>Greater engagement from health department (HD) with territory wide policies, will lead to greater coverage. Greater push to solve information systems, testing and logistical challenges.</p> <p>HD could centralize testing at reference lab facilitating testing and result logistics with phased implementation. Removes some burden of testing/vaccination from providers.</p> <p>May lead to implementation of dengue vaccine programs in other countries with high dengue burden.</p>	<p>May allow for quicker, but limited use of the vaccine.</p> <p>Theoretically allows for more careful discussion between provider and parents. May lead to full recommendation later after vaccine gains are more acceptable. Places the burden on providers leading to delays and missed opportunities for testing/vaccination.</p> <p>This path may be a “dead end” for this vaccine and any other unbalanced dengue vaccines that still have benefit.</p>

# Routine versus shared decision making

Attribute	Routine recommendation	Shared decision making
Health Equity	Would increase health equity.	Likely decreased health equity. Only empowered and informed patients or those served by informed pediatricians would have access to the vaccine. Administrative hurdles and costs will reduce access for families with low-medical literacy and economic means.
Education of providers and families	Educational materials for families and training of providers more readily available.	CDC efforts on educating providers and patients with less buy-in from HD.
Cost-effectiveness	Can be cost effective in most scenarios.	Will not be cost-effective.

# Routine versus shared decision making

Attribute	Routine recommendation	Shared decision making
Communication and media	<p>Communication will fall to HD and CDC and will be challenging.</p> <p>Hospitalizations among all vaccinees will have to be explained. These hospitalizations will be mainly due to vaccine breakthrough and only a small percentage will be due to vaccinating seronegatives, but clinicians and the public may attribute all hospitalizations to the vaccine.</p> <p>Faulty implementation may lead to negative perception of dengue vaccines and vaccines in general, a particular concern in the midst of efforts to achieve high coverage for COVID vaccines.</p>	<p>Slow implementation and limited coverage would make public relations issues less likely.</p> <p>Vaccine safety concerns may vary by individual so that shared decision making would lessen fears that the vaccine will become controversial and a stimulus to vaccine hesitancy.</p>

## Option 2: Shared decision making

### Cons

- Lower uptake
- Little progress in sorting out feasibility
- Coverage of test by insurance companies challenging
- May increase health inequities
- Less buy-in for large scale education and communication

### Pros

- Would lessen fears that the vaccine will become controversial and result in increased vaccine hesitancy

# Option 3: Routine recommendation

## Cons

- Perception all hospitalizations among vaccinees related to vaccine, but most hospitalizations related to vaccine breakthrough
- Media backlash could reduce coverage for other vaccines

## Pros

- Useful vaccine for seropositives. Sustainable vector control for *Aedes aegypti* is still years off in the U.S. while dengue outbreaks continue to occur
- Greater coverage, reduction in hospitalizations.
- Better buy-in from health department and immunization program to resolve challenges with feasibility
- Broader communication and media campaign
- Increase in health equity

# Policy options for ACIP consideration

- ACIP does not recommend the intervention (Intervention may be used within FDA licensed indications)
- ACIP recommends the intervention for individuals based on shared clinical decision-making
- ACIP recommends the intervention





# Draft Recommendation

- ACIP recommends 3-doses of Dengvaxia administered in persons 9-16 years of age with laboratory confirmation of previous dengue infection and living in endemic areas.

# ACIP Dengue Vaccines Workgroup

## ACIP Members

Kathy Poehling (Co-chair)

Wilbur Chen (Co-Chair)

Beth Bell

Veronica McNally

## CDC Lead

Gabriela Paz-Bailey

## Ex Officio Members

Kaitlyn Morabito (NIH)

Ralph LeBlanc (FDA)

Kirk Prutzman (FDA)

Srihari Seshadri (DOD)

## Liaison Representatives

Elizabeth Barnett (AAP)

Rob Schechter (AIM)

## Consultants

Edwin Asturias

Robert Atmar

Alan Barrett

Anna Durbin

Ines Esquilin

Tony Marfin

Hal Margolis

Kristen Pierce

Anita Shet

Steve Waterman

## CDC Contributors

Laura Adams

Josh Wong

Mimi Eckert

Rachel Eidex

Susan Hills

Terri Hyde

Mike McNeil

Jorge Munoz

Erin Staples

Cindy Weinbaum